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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/139,386	08/25/1998	JOSEPH ALBERT MONFORTE	GETR.031-STA	5243

7590

04/10/2002

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EXAMINER

TUNG, JOYCE

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 04/10/2002

LS

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.  
**09/139,386**

Applicant(s)  
**Monforte et al.**

Examiner  
**Joyce Tung**

Art Unit  
**1637**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on Jan 25, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 24 20) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1637.

#### ***Request for Continued Examination***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/25/2002 has been entered.

#### ***Double Patenting***

2. Claims 1-21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 5,700,642 and claims 15 and 17-18 of U.S. Patent No. 5,830,655. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-19 of U.S. Patent No. 5,700,642 are drawn to a method to determining the size of a primer extension product and claims 15 and 17-18 of U.S. Patent No. 5,830,655. Both U.S. Patents involves using the primer which has the same features as claimed in instant claims 1-21. It would have been prima facie obvious to an

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ordinary skill in the art at the time of the instant invention to claim the nucleic acid primer which has the same features as used in the methods of U.S. Patent No. 5,700,642 and 5,830,655.

***Information Disclosure Statement***

3. The references lined through have not been considered because the references were not provided in the application.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

5. Claims 1-9, 11-14, and 20-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Koster (5,622,824).

Koster discloses a nucleic acid primer having a 5' end and 3' end comprising:

- (a) a first region containing the 5'end of the primer and an immobilization attachment site (See column 7, lines 62-67 and column 8, line 1) and;

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(b) a second region containing the 3' end of the primer and a chemically cleavable site, wherein the 3' end is capable of being extended by an enzyme (See column 8, lines 13-14 and lines 37-54).

The teachings of Koster are also inherent the limitations of claims 2-9 which further limit to claim 1 in that the chemically cleavable site is located at or within about five nucleotides from the 3' end of the primer (See column 13, lines 5-9), the chemically cleavable site comprises a modified sugar (See column 7, lines 40-60), is selected from the group consisting of phosphorothioate, and uracil as listed in claim 7 (See column 12, lines 49-67 and column 18, lines 1-2).

The teaching of Koster are further inherent the limitations of claims 11-14 and 20-21 in that the 3' end is capable of being extended by a ligase, immobilization attachment site is attached to an intervening spacer arm with six or more atoms in length bound to the solid support, the immobilization attachment site comprises a single stranded nucleic acid which is complementary to an intermediary oligonucleotide bound to the solid support and the primer is attached to the solid support by hybridization of the immobilization attachment site to the intermediary oligonucleotide (as recited in claims 20 and 21) (See column 7, lines 62-67 and column 8, lines 1-19), the solid support is selected from the group consisting of glass, silicon, polystyrene and gold as listed in claim 14 (See column 8, lines 21-26).

Thus, the teachings of Koster anticipate the limitations of claims 1-9, 11-14, and 20-21.

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***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koster (5,622,824) as applied to claims 1-9, 11-14, and 20-21 above, and further in view of Koster (5,547,835).

The teachings of Koster (5,622,824) are set forth in section 5 above and Koster (5,622,824) does not teach that the solid support comprises a functionality selected from the group consisting of avidin and streptavidin, antibody and anti-antibody.

Koster (5,547,835) disclose that the linker chemistry on the solid support can be a biotin/streptavidin system (see column 13, lines 15-31).

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One of ordinary skill in the art at the time of the instant invention would have been motivated to apply the biotin/streptavidin system as taught by Koster (5,547,835) because the method of Koster (5,547,835) is high speed and high throughput and this indicates that the biotin/streptavidin system for the linker chemistry is very effective. It would have been prima facie obvious to make the primer as claimed.

8. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Koster (5,547,835) as applied to claims 1-9, 11-14, and 20-21 above, and further in view of Richards et al. (5,427,929).

The teachings of Koster (5,622,824) are set forth in section 5 above and Koster (5,622,824) does not teach that the ligase enzyme involved.

Richards et al. disclose a method which involves a ligase chain reaction (See column 11, lines 2-9) and a primer comprising 3' end cleavable site (See column 16, lines 65-68 to column 17, 1-5).

One of ordinary skill in the art at the time of the instant invention would have been motivated to use a ligase in a nucleic acid polymerization reaction as taught by Richards et al. because the method of Richards et al. is efficient and economy for reducing carryover contamination in an amplification procedure (See the Abstract). It would have prima facie obvious to make the primer as claimed.

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9. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1656 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

April 6, 2002

  
GARY BENZION, PH.D.  
SUPERVISORY PATENT EXAMINER  
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